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(54) Title: DEVICE FOR ALTERING CORNEAL REFRACTIVE PROPERTIES
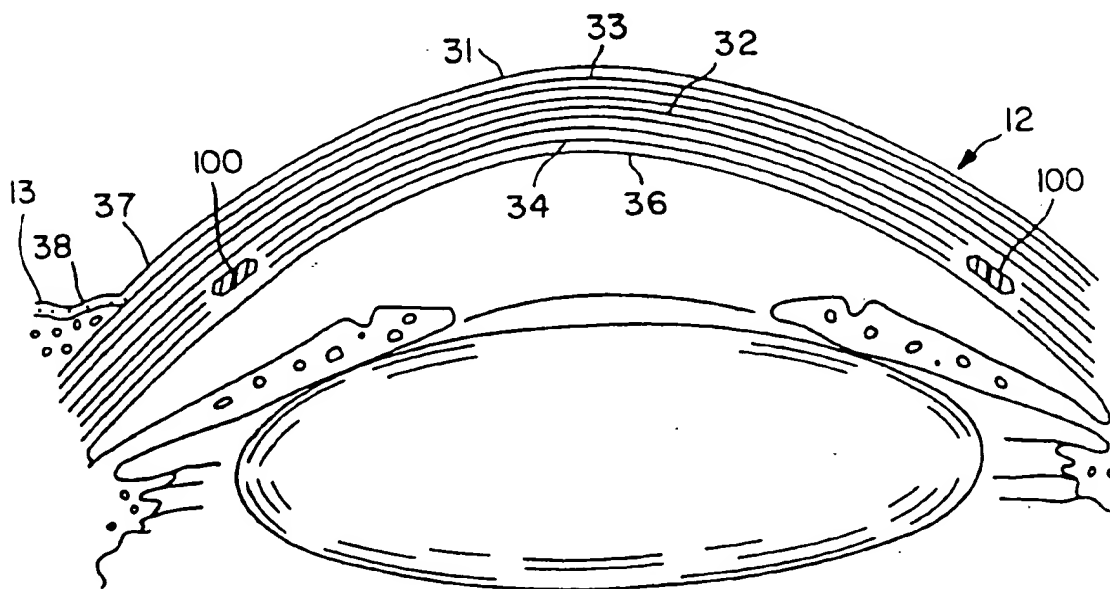
(57) Abstract

This invention is a device (100) for refractive correction of the eye in order to improve the vision of the eye (12). The device (100) is an intra-stromal corneal ring (ICR) where the cone angle (N) is varied according to the desired aspheric shape of the eye.

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5   DEVICE FOR ALTERING CORNEAL REFRACTIVE PROPERTIES

Description

Technical Field

10   This invention is in the general field of
medical technology and relates specifically to a device
and method for varying the curvature of the cornea of the
eye in order to correct vision problems. The device is
an intrastromal corneal ring which is inserted into the
15   cornea and varies the radius of curvature and/or the
aspheric shape of the cornea as a function of the cone
angle of the device.

Background

20   Anomalies in the shape of the eye can cause
visual disorders. Axial hyperopia ("farsightedness")
occurs when the front-to-back distance in the eyeball is
too small. Curvature hyperopia occurs when the corneal
curvature is less than normal and therefore is flatter
25   than the normal cornea. In these cases, parallel rays
originating greater than 20 feet from the eye focus
behind the retina. In contrast, when the front-to-back
distance of the eyeball is too large, axial myopia
("nearsightedness") occurs. When the corneal curvature
30   is too great, curvature myopia occurs. In these cases,
the focus of parallel rays entering the eye occurs in
front of the retina. Astigmatism is a condition which
occurs when the parallel rays of light do not focus to a
single point within the eye, but rather have a variable
35   focus due to the fact that the corneal curvature varies

in different meridians. Light is therefore refracted different distances and focuses at different regions. Some degree of astigmatism is normal, but where astigmatism is too pronounced, it must often be

5   corrected. Presbyopia is an age-related condition that results in the loss of the ability of the eye to change focal length.

Hyperopia, myopia, presbyopia and astigmatism are usually corrected by glasses or contact lenses.

10   Surgical methods for the correction of such disorders have been cited in the literature and include radial keratotomy (see e.g. U.S. Patents Nos. 4,815,463 and 4,688,570) and laser corneal ablation (see e.g. U.S. Patent No. 4,941,093). Another method for correcting

15   those disorders is through implantation of polymeric rings in the eye's corneal stroma to change the curvature of the cornea. Previous work involving the implantation of polymethylmethacrylate (PMMA) rings, allograft corneal tissue and hydrogels is well documented. One of the ring

20   devices involves a ring design that allows a split ring to be inserted into a channel dissected in the stromal layer of the cornea. The device uses a minimally invasive incision through which the channel for the implant is created and through which the implant is

25   inserted and adjusted. Adjustment of the device normally involves an adjustment of ring size or diameter.

U.S. Patent No. 4,452,235 describes a method and apparatus for corneal curvature adjustment. The method involves inserting one end of a split end

30   adjusting ring into the cornea of the eye and moving the ring in a circular path until its ends meet. The ends are thereafter adjusted relative to each other until the shape of the eye has assumed a desired curvature whereupon the ends are fixedly attached to maintain the

35   desired curvature of the cornea.

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PCT/US93/00059, the entirety of which is .
incorporated by reference, describes a method for the
refractive correction of the eye as well. Intrastromal
corneal rings of varying thickness are inserted into the
5   corneal stroma to change the curvature of the cornea.

The present invention involves the use of
intrastromal corneal rings of varying cone angles to
change the curvature of the cornea for the refractive
adjustment of the eye.

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Summary of the Invention

This invention is to an intrastromal corneal
ring (ICR) for varying the curvature and/or the aspheric
shape of the cornea of an eye typically for the purpose
15   of improving the vision of the eye. The ICR is a split
polymeric ring and is adapted to substantially encircle
the cornea. The ICR has a thickness of desirably between
about 0.05 and 0.60 mm and a cone angle above about
22.5°. The cone angle is chosen based on the starting
20   curvature of the eye and on the thickness of the ICR and
the type of aspheric shape desired.

In a further aspect, the invention is to a
method for varying the curvature of the cornea of an eye
again typically for the purpose of improving the vision
25   of the eye. The method involves inserting an
intrastromal corneal ring having a thickness desirably
between about 0.05 and 0.60 mm and a cone angle between
about 0° and 50° into the corneal stroma to increase the
radius of corneal curvature and/or change the aspheric
30   shape of the cornea. Such method may be useful in the
treatment of myopia, presbyopia and astigmatism.

Brief Description of the Drawings

Figure 1 is a schematic representation of a
35   horizontal section of the eye.

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Figure 2 is a schematic illustration of the anterior portion of the eye showing the various layers of the cornea.

Figure 3 is a schematic representation of an eye showing the average corneal curvature radius and aspheric shape of the cornea.

Figure 4 is a schematic representation of a myopic eye showing the average corneal curvature radius and the aspheric shape of the cornea.

Figure 5 is a plan view of an ICR of the invention.

Figure 6 is an cross sectional view of an ICR of the invention.

Figure 7 is a graph showing the cone angle "N" to be used with ICRs of varying thickness.

Figures 8A, 9A, 10A, 11A, 12A, 13A, and 14A are corneal maps that show the change in topography of the cornea when ICRs of differing thickness and a 34° cone angle are implanted into a cadaver eye. Figures 8B, 9B, 10B, 11B, 12B, 13B, and 14B are corneal maps that show the change in the topography of the cornea as observed in two different planes that are 90° apart.

Like elements in the drawings bear the same reference numerals.

Modes for Carrying Out the Invention

Prior to explaining the details of the inventive devices and methods, a short explanation of the physiology of the eye is needed to appreciate the functional relationship of the device to the eye.

Figure 1 shows a horizontal section of the eye with the globe (11) of the eye resembling a sphere with an anterior bulged spherical portion representing the cornea (12).

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The globe (11) of the eye consists of three concentric coverings enclosing the various transparent media through which the light must pass before reaching the sensitive retina (18). The outermost covering is a

5   fibrous protective portion the posterior five-sixths of which is white and opaque and called the sclera (13), and sometimes referred to as the white of the eye where visible to the front. The anterior one-sixth of this outer layer is the transparent cornea (12).

10   A middle covering is mainly vascular and nutritive in function and is comprised of the choroid (14), ciliary body (16) and iris (17). The choroid (14) generally functions to maintain the retina (18). The ciliary body (16) is involved in suspending the lens (21)

15   and accommodation of the lens. The iris (17) is the most anterior portion of the middle covering of the eye and is arranged in a frontal plane. It is a thin circular disc corresponding to the diaphragm of a camera, and is perforated near its center by a circular aperture called

20   the pupil (19). The size of the pupil varies to regulate the amount of light which reaches the retina (18). It contracts also to accommodation, which serves to sharpen the focus by diminishing spherical aberration. The iris (17) divides the space between the cornea (12) and the

25   lens (21) into an anterior chamber (22) and posterior chamber (23). The innermost portion of covering is the retina (18), consisting of nerve elements which form the true receptive portion for visual impressions.

The retina (18) is a part of the brain arising

30   as an outgrowth from the fore-brain, with the optic nerve (24) serving as a fiber tract connecting the retina part of the brain with the fore-brain. A layer of rods and cones, lying just beneath a pigmented epithelium on the anterior wall of the retina serve as visual cells or

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photoreceptors which transform physical energy (light) into nerve impulses.

The vitreous body (26) is a transparent gelatinous mass which fills the posterior four-fifths of the globe (11). At its sides it supports the ciliary body (16) and the retina (18). A frontal saucer-shaped depression houses the lens.

The lens (21) of the eye is a transparent bi-convex body of crystalline appearance placed between the iris (17) and vitreous body (26). Its axial diameter varies markedly with accommodation. A ciliary zonule (27), consisting of transparent fibers passing between the ciliary body (16) and lens (21) serves to hold the lens (21) in position and enables the ciliary muscle to act on it.

Referring again to the cornea (12), this outermost fibrous transparent coating resembles a watch glass. Its curvature is somewhat greater than the rest of the globe and is ideally spherical in nature. However, often it is more curved in one meridian than another giving rise to astigmatism. A central third of the cornea is called the optical zone with a slight flattening taking place outwardly thereof as the cornea thickens towards its periphery. Most of the refraction of the eye takes place through the cornea.

Referring to Figure 2, a more detailed drawing of the anterior portion of the globe shows the various layers of the cornea (12) comprising an epithelium (31). Epithelial cells on the surface thereof function to maintain transparency of the cornea (12). These epithelial cells are rich in glycogen, enzymes and acetylcholine and their activity regulates the corneal corpuscles and controls the transport of water and electrolytes through the lamellae of the stroma (32) of the cornea (12).

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An anterior limiting lamina (33), referred to as Bowman's membrane or layer, is positioned between the epithelium (31) and the stroma (32) of the cornea. The stroma (32) is comprised of lamella having bands of

5   fibrils parallel to each other and crossing the whole of the cornea. While most of the fibrous bands are parallel to the surface, some are oblique, especially anteriorly. A posterior limiting lamina (34) is referred to as Descemet's membrane. It is a strong membrane sharply

10   defined from the stroma (32) and resistant to pathological processes of the cornea.

The endothelium (36) is the most posterior layer of the cornea and consists of a single layer of cells. The limbus (37) is the transition zone between

15   the conjunctiva (38) and sclera (13) on the one hand and the cornea (12) on the other.

Figure 3 shows the globe of the eye having a cornea (12) with an average spherical radius of curvature (41) and a positive aspheric shape. By "average

20   spherical radius of curvature" we intend the radius of the circle defined by the points at the periphery (45) of the cornea near the limbus of the eye and having a center (46). By "positive aspheric shape" we mean that the distance (47) from that center (46) to the anterior

25   center of the cornea is greater than the average spherical radius of curvature, that is, the anterior surface of the cornea flattens as it progresses from the center (44) to its periphery (45). As shown in Figure 3, when parallel rays of light pass through the corneal

30   surface, they are refracted by the corneal surfaces to converge eventually near the retina (18) of the eye. The diagram of Figure 3 discounts, for the purposes of this discussion, the refractive effect of the lens or other portions of the eye.

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          The eye depicted in Figure 4 is myopic because
the light rays from the periphery of the cornea refract
into focus at a point in the vitreous body which is in
front of the retinal surface. Further, the eye depicted
5   in Figure 4 has does not have the same aspheric shape as
that shown in Figure 3. The distance (47) from the
center (46) to the anterior surface of the cornea is
about the same as or less than the average spherical
radius of curvature (41) and thus the cornea does not
10   flatten from center (44) to periphery (45) but rather
plateaus or even dips at its center. If an ICR is
implanted into the cornea shown in Figure 4, the light
rays refracted by the now flattened corneal surface will
be refracted at a smaller angle and thus converge at a
15   more·distant point such as directly on the retina.
Further, selection of an ICR having an appropriate cone
angle may allow for the eye to obtain a more positive
aspheric shape similar to that shown in the Figure 3 eye.
          With the background discussion of Figures 1-4
20   in hand, it should be understood that the device and
method of the present invention is for the adjustment of
at least a portion of an annular chord of the cornea to
decrease the radius of curvature and/or change the shape
of the cornea in order to improve the vision of the eye.
25   We have found that the shape of the anterior corneal
surface may be adjusted by using ICR's having varying
"cone angles". The cone angle "N" of the ICR is shown as
angle N in Figure 6. Cone angle "N" is defined as the
angle between the plane of the flat surface that the ICR
30   rests on and a line drawn between the point of the cross-
section that rests on the flat surface and the point on
the cross-section that is farthest from the point where
the ICR rests on the flat surface. The cross-section
referred to is one that cuts through the diameter of the
35   ICR and is at an angle of 90° to the flat surface.

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Previously, the cone angle N was generally considered appropriate at a fixed value equal to about 22 5°. This angle was selected to be one which would generally be tangential to the corneal anterior surface

5   at the front surface of the installed ICR. We have now found that by varying the cone angle, the rate of change of the radius of curvature of the cornea progressing from the center to the periphery of the cornea can be adjusted such that the cornea assumes an aspheric profile that may

10   closely match the positive aspheric shape shown in Figure 3, depending on the cone angle chosen and the natural shape of the cornea. The cone angle N will be above 22.5°, preferably it will be between about 23° and 50°, preferably it will be between about 23° and 35°. Such a

15   ring placed, for instance, approximately at the 8 mm chord of the cornea provides a means for adjusting the radius of curvature of the cornea so that vision is improved. Other placements will depend on the physical dimensions of the particular eye to be implanted.

20   By selecting the thickness of the ring according to the amount of corrective refraction desired, the rays refracted by the cornea and other eye components may be brought to focus directly on the retina. The cone angle N may be selected to maintain the aspheric shape of

25   the eye prior to insertion of the ring. In other cases, the cone angle N may be selected to alter the aspheric shape of the eye.

               Figure 5 shows one desirable ICR made according to the invention. The ICR is comprised of a generally

30   circular member having split end portions. The material should have properties that render it physiologically compatible with the tissue of the cornea. An illustrative material is a plastic type material sold under the trade name of PERSPEX CQ™ (Imperial Chemical

35   Company, England), however many other biocompatible

polymers including but not limited to Teflon, PMMA and polysulfones are useful in the invention. One acceptable cross sectional shape of the rings is the hexagonal shape shown in Figure 6 and is generally dimensioned to be

5   about 0.5 mm to 2.0 mm from point to point (dimension "x") and from about 0.05 mm to 0.60 mm in thickness (dimension "y"). Rings of other cross-sectional shapes including but not limited to ovoloid and rectangular shapes may be useful in the invention as well.

10   Even where the eye is not myopic, the method of the present invention may be useful to change the radius of curvature of the central cornea and the aspheric shape of the cornea. Generally speaking, where it is desirable to obtain a flatter central corneal curvature without

15   changing ICR thickness, an ICR with a higher degree cone angle (e.g. 34° rather than 25°) will be implanted. Where, however it is desirable to maintain the aspheric shape existing prior to insertion of the ICR, an ICR with an appropriate cone angle should be employed,

20   particularly as the ICR thickness is increased and the curvature of the eye is flattened overall. One example of a guide to ICRs having coordinated cone angles and related ICR thicknesses is shown in Figure 7. Insertion of such rings into a "theoretical 43 diopter" eye

25   provides correction between -0.5 and -13.5 diopters without significantly altering the asphericity of the eye. However, the relationship of cone angle to thickness may vary from eye to eye since the initial diameter and corneal curvature of the eye may also vary.

30   According to Figure 7, where the thickness of the ICR for example is 0.20 mm, the cone angle will be between about 28° and 34°, for 0.25 mm, the cone angle will be between about 27.5° and 33.5°, for 0.30 mm, the cone angle will be between about 27° and 33°, for 0.35 mm, the cone angle

35   will be between about 26° and 32°, for 0.40 mm, the cone

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angle will be between about 25.5° and 31.5°, for 0.45 mm,
the cone angle will be between about 24.5° and 30.5°, for
0.50 mm, the cone anɣle will be between about 24° and
30°, and where the thickness of the ICR is 0.55 mm, the
5   cone angle will be between about 23.5° and 29.5°.

In the method of the invention for the
correction of myopia, the physician will determine the
amount of corrective refraction necessary to improve a
patient's vision. From the determination of the
10   necessary corrective refraction, the physician will
choose an ICR with the appropriate thickness and cone
angle to obtain the corneal curvature radius desired.
The thickness will be between about 0.05 mm and 0.60 mm
and the cone angle will be between 0° and 50°, preferably
15   between about 18° and 50°, or between about 23° and 50°,
or between about 23° and 35°. The ring may be installed
in the inner lamellar regions of the corneal stroma by
any of the methods we have shown in the past to be
suitable for such installation. Particularly desired is
20   the process and its allied apparatus shown in
PCT/US93/03214 which is incorporated herein by reference
in its entirety. In general, the ring is installed in
the following manner: A small radial incision is made at
the radius in which the ring is ultimately to be
25   installed about the cornea. A dissector in the form of a
split ring and having a point suitable for producing an
interlamellar channel or tunnel in the corneal stroma is
introduced through the small incision and rotated in such
a fashion that a generally circular channel is formed
30   completely about the cornea. The dissector is then
rotated in the opposite direction to withdraw it from the
tunnel thus formed. The ICR is then introduced into the
circular channel. Similar methodology will be used for
the treatment of astigmatism and presbyopia.

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In a further method for the correction of
myopia, the physician will determine the amount of
corrective refraction necessary to improve a patient's
vision and from this determination will choose an ICR
5 with the appropriate thickness to obtain the corneal
curvature radius desired. In addition, the cone angle of
the ICR is chosen to change the aspheric shape such that
the cornea flattens more from center to periphery. The
cone angle and thickness is as described above. The ring
10 may be installed in the inner lamellar regions of the
corneal stroma as described above.

In yet another method for the correction of
myopia, the physician will determine the amount of
corrective refraction necessary to improve a patient's
15 vision and from this determination will choose an ICR
with the appropriate thickness to obtain the corneal
curvature radius desired. In addition, the cone angle is
chosen to maintain the aspheric shape of the eye close to
prior to implantation of the ICR. Again, the cone angle
20 and thickness of the ring are as described above and the
ring may be installed in the inner lamellar regions of
the corneal stroma as described above.

In yet one more method for the corrective
refraction of an eye, where it is desirable to obtain or
25 maintain a particular aspheric shape, the ICR of
particular thickness and cone angle may be implanted and
the aspheric shape measured by using, for instance, a
Kerametrics Class II Corneal Surface Analyzer. The
instrument measures the corneal surface in terms of
30 deviation from a spherical shape of a particular size.
In Figures 8A, 9A, 10A, 11A, 12A, 13A, and 14A,
measurement of a sphere would result in a graph having a
rounded plateau or "mesa". Any deviation from the
spherical baseline shows up on that three-dimensional
35 depiction as a variance from that plateau. Figures 8B,

9B, 10B, 11B, 12B, 13B and 14B show both the shape of the
baseline "sphere" and the deviation from the spherical
baseline in two-dimensional depictions. Where the
measured aspheric shape is not as desired, the ICR will
5   be removed and the ICR with appropriate cone angle will
be implanted.

The following Examples are intended to further
illustrate but not to limit the invention in any manner.
10   In each of the Examples below, the cross-sectional shape
of the ICR was hexagonal and the ICR ends were not
joined.

Example 1

15   This Example shows the relationship between ICR
thickness and cone angle and the variation of the shape
of the anterior corneal surface when an eye is implanted
with ICRs of varying thickness that have the same cone
angles.
20   In order to define the corneal topography that
results from the ICR cone angle effect, ICRs with
thicknesses of 0.25, 0.30, 0.35 and 0.40 mm with constant
cone angles of 34° were implanted into a deturgesced
cadaver eye. The corneal topography of the eye was
25   measured before and after ICR implantation using the
Kerametrics Class II Corneal Surface Analyzer. The
Analyzer uses laser holographic interferometry to measure
corneal topography.
          Figures 8-12 A and B show the corneal
30   topography of an eye prior to and after being implanted
with ICRs of varying thickness. Figur 8A shows the
aspherical topography in three dimens: 3 a: Figure 8B
shows the topography as observed in two different planes
that are 90° apart. Both Figures show the topography of
35   the eye in terms of deviation from a spherical shape

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before implantation of an ICR. As is evident from the
top right portion of Figure 8A, the eye has a
nonsymmetrical aspheric shape, but it is normal in that
the corneal curvature generally flattens from the center
5   to the periphery.

Figures 9A and 9B show the eye after
implantation with a 0.25 mm thick ICR. The aspheric
shape has been maintained close to the original aspheric
shape in what is considered to be a normal aspheric shape
10   in that the curvature flattens from the center to the
periphery.

Figures 10A and 10B show the eye after
implantation with a 0.30 mm thick ICR. Figures 11A and
11B show the eye after implantation with a 0.35 mm thick
15   ICR. Implantation of both the 0.30 mm and 0.35 mm thick
ICRs produce less curved but still acceptable aspheric
shapes. Figures 12A and 12B show the eye after
implantation with a 0.40 mm thick ICR. These figures
show an aspheric shape that does not flatten from center
20   to periphery but bulges in the upper quadrant shown in
Figure 12A. Such result indicates that an ICR with a
cone angle below 34° should be employed to produce a
aspheric shape that flattens from center to periphery.

In sum, Figures 6-12 A and B indicate that the
25   degree of change of the central corneal curvature can be
carefully tuned depending on the cone angle and thickness
of the ICR chosen.

Example 2

30   This Example shows the relationship between ICR
thickness and cone angle and the variation of the
anterior corneal surface based on constant thickness and
varying cone angle.

A 0.40 mm thick ICR with a 25° cone angle was
35   inserted into the eye. The corneal topography of the eye

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is shown in Figures 13A and 13B. Introduction of the ICR
produced a desirable aspheric shape. Removal of the 25°,
0.40 mm ICR and replacement with a 34°, 0.40 mm ICR
resulted in a much flatter central cornea (see Figures

5   14A and 14B). Therefore, to produce an aspheric shape
that flattens more from center to periphery, an ICR with
a smaller cone angle would be used for this eye.

       Modifications of the above described modes for
10   carrying out the invention that are obvious to persons of
skill in the fields of medicine, ophthalmology, optometry
and/or related fields are intended to be within the scope
of the following claims.

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Claims

We claim:

1. An intrastromal corneal ring (ICR) for introduction into the cornea of an eye, said ICR comprising a split polymeric ring adapted to substantially encircle the cornea, said ICR having a cone angle above about 22.5°.

2. The intrastromal corneal ring (ICR) of claim 1 wherein the cone angle is between about 23° and 50°.

3. An intrastromal corneal ring (ICR) useful for refractive correction of an eye for the purpose of improving the vision of said eye by changing the radius of curvature of said eye, said intrastromal corneal ring having a thickness of between about 0.05 and 0.60 mm and cone angle between about 0° and 50°.

4. An intrastromal corneal ring (ICR) useful for refractive correction of an eye for the purpose of improving the vision of said eye by changing the aspheric shape of the cornea of the eye, said intrastromal corneal ring having a thickness of between about 0.05 mm and 0.60 mm and a cone angle between about 0° and 50°.

5. An intrastromal corneal ring (ICR) useful for refractive correction of an eye for the purpose of improving the vision of said eye, said intrastromal corneal ring having a thickness of between about 0.05 and 0.60 mm and a cone angle of between about 0° and 50°, said cone angle selected to maintain the asphericity of the eye close to the asphericity of the eye prior to insertion of the intrastromal corneal ring.

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6.   The ICR of claims 3, 4 or 5 wherein the cone angle is between about 18° and 50°.

7.   The ICR of claim 5 wherein the thickness
5   of the ICR is 0.20 mm and the cone angle is be between about 28° and 34°.

8.   The ICR of claim 5 wherein the thickness of the ICR is 0.25 mm and the cone angle is between about
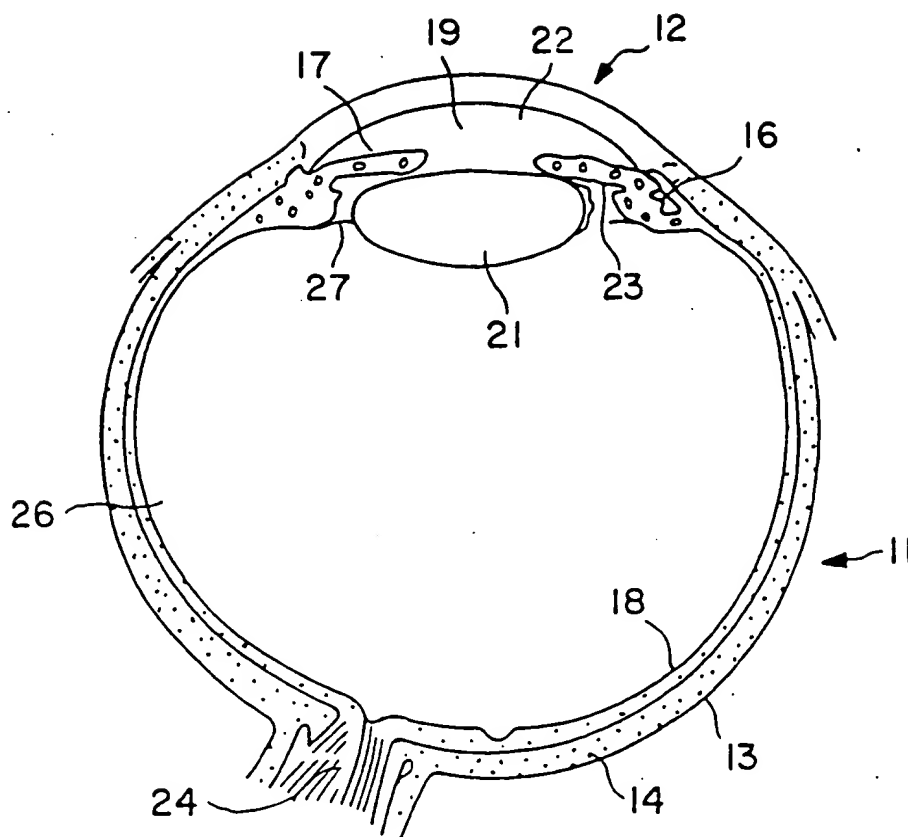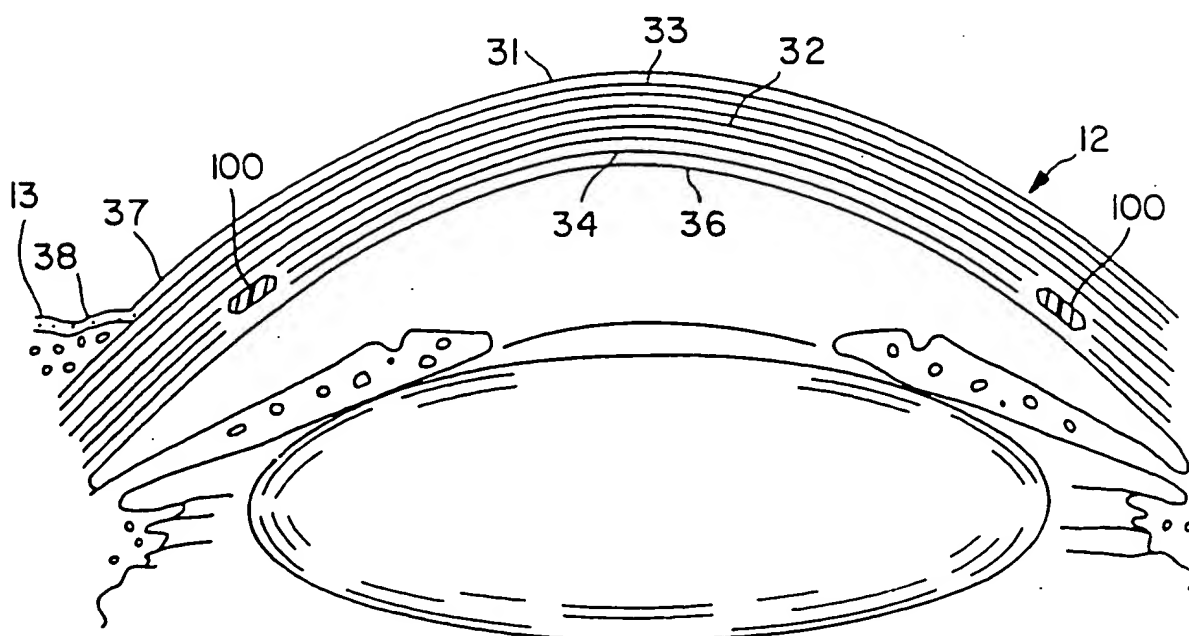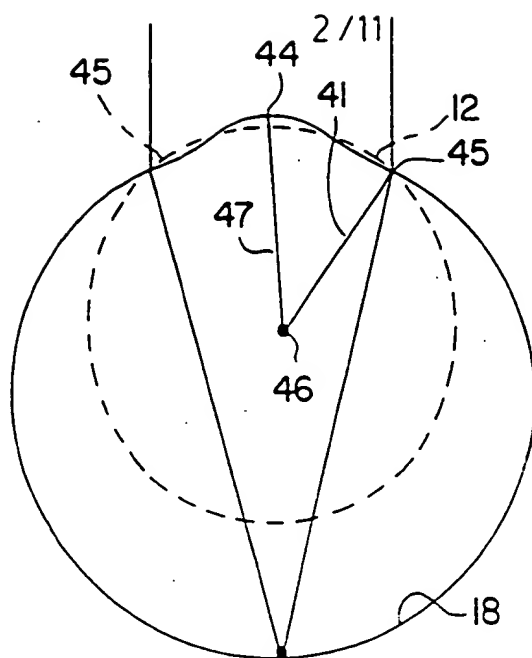10   27.5° and 33.5°

9.   The ICR of claim 5 wherein the thickness of the ICR is 0.30 mm and the cone angle is between about 27° and 33°.

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10.   The ICR of claim 5 wherein the thickness of the ICR is 0.35 mm and the cone angle is between about 26° and 32°.

20   11.   The ICR of claim 5 wherein the thickness of the ICR is 0.40 mm and the cone angle is between about 25.5° and 31.5°.

12.   The ICR of claim 5 wherein the thickness
25   of the ICR is 0.45 mm and the cone angle is between about 24.5° and 30.5°.

13.   The ICR of claim 5 wherein the thickness of the ICR is 0.50 mm and the cone angle is between about
30   24° and 30°.

14.   The ICR of claim 5 wherein the thickness of the ICR is 0.55 mm and the cone angle is between about 23.5° and 29.5°.
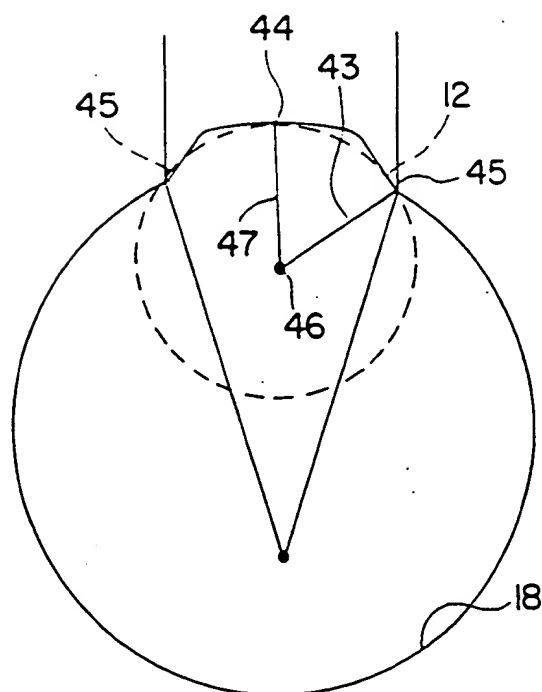
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FIG. 1

FIG. 2

F I G. 3

F I G. 4
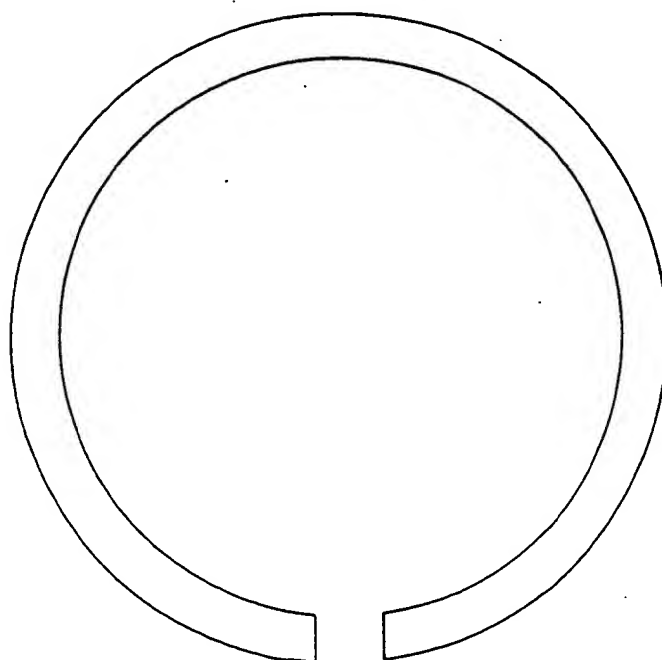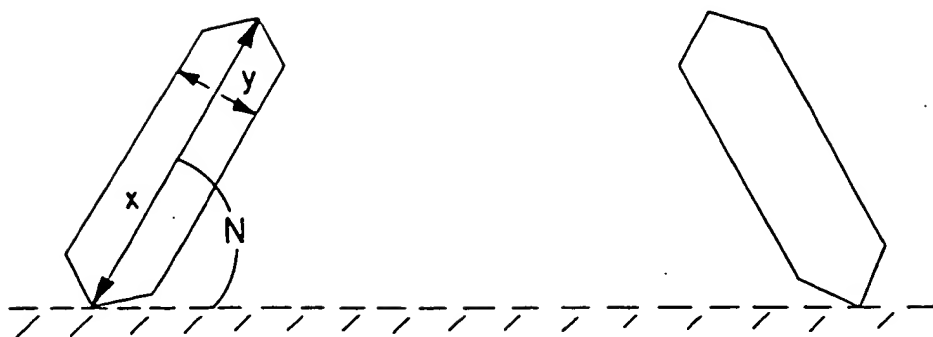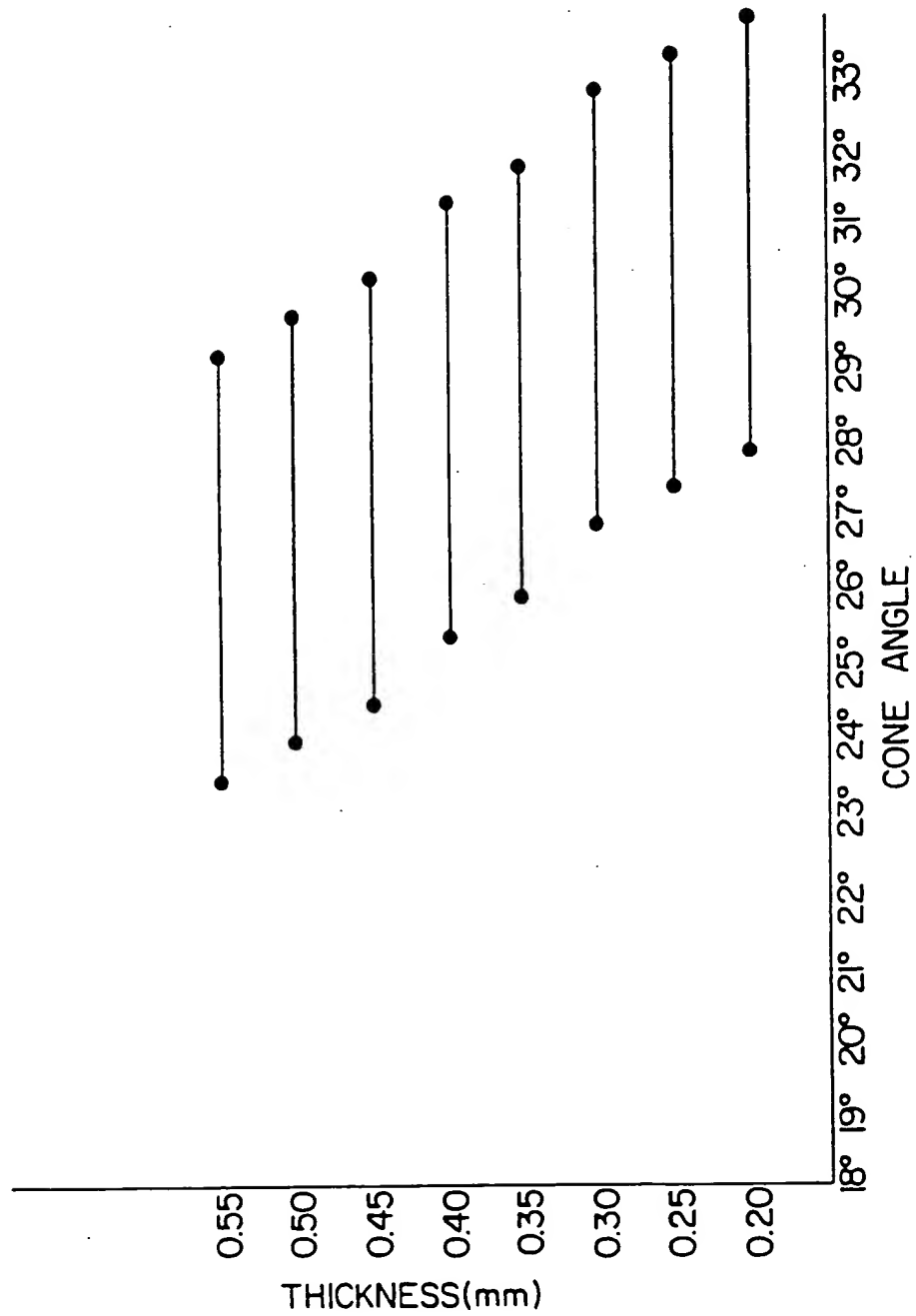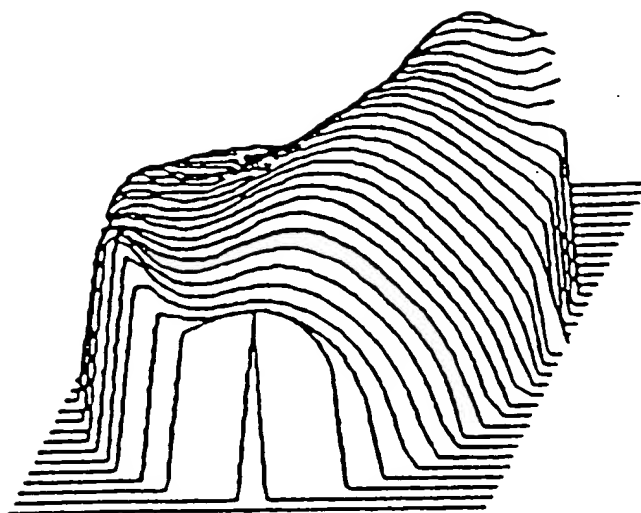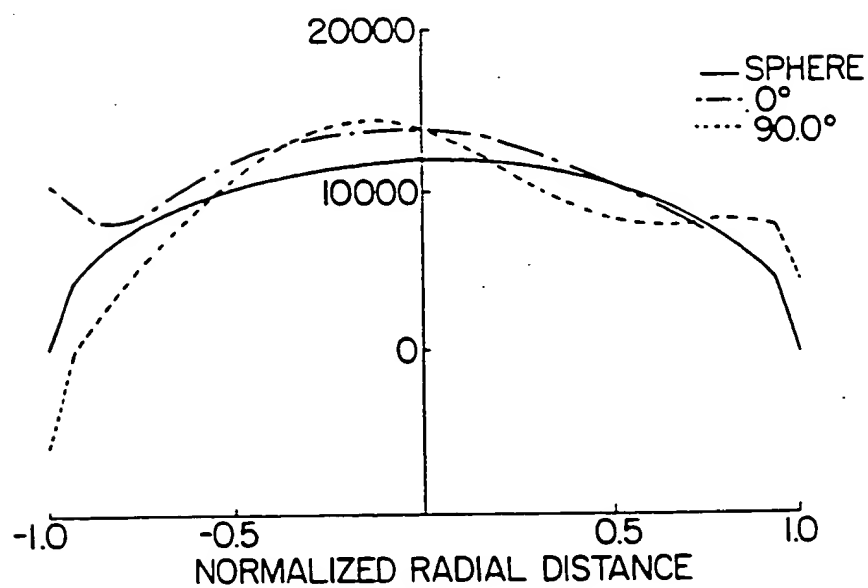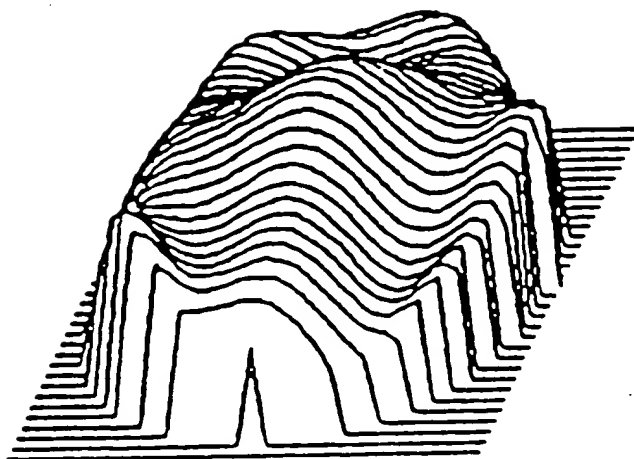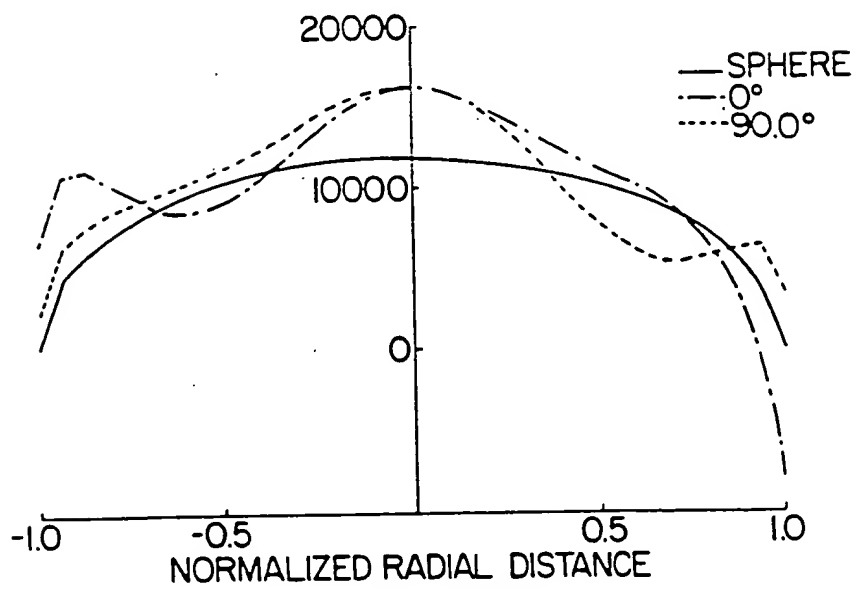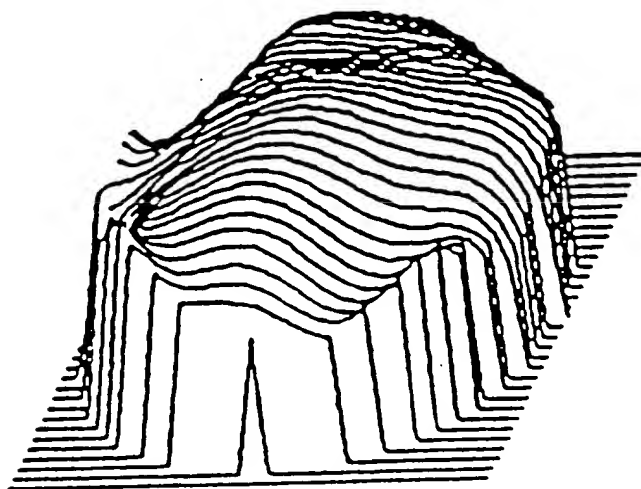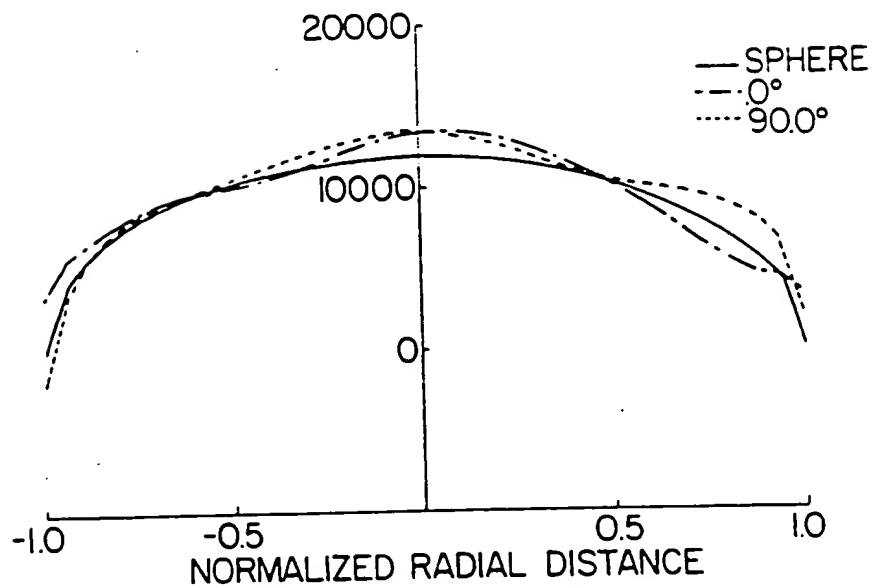
F I G. 5

F I G. 6

FIG. 7

THICKNESS(mm)

CONE ANGLE

F I G. 8A

F I G. 8B

F I G. 9A

F I G. 9B

F I G. IOA

F I G. IOB

8/11

F I G. I I A

F I G. I I B

F I G.   12 A

20000

SPHERE
0°
90.0°

10000

0

-1.0   -0.5   0.5   1.0
NORMALIZED RADIAL DISTANCE

F I G.   12B

F I G. 13A

NORMALIZED RADIAL DISTANCE

F I G. 13B

F I G. 14A

NORMALIZED RADIAL DISTANCE
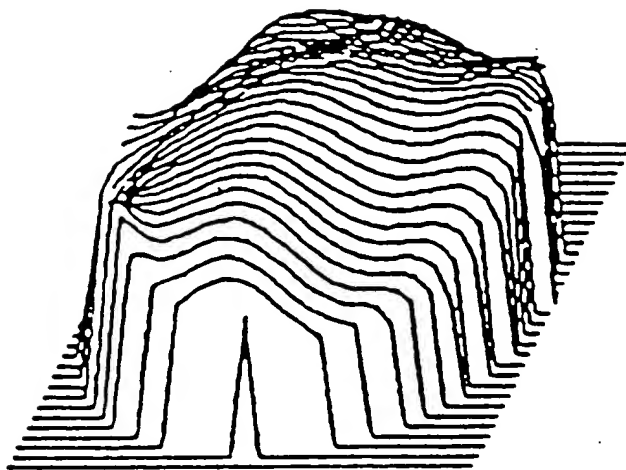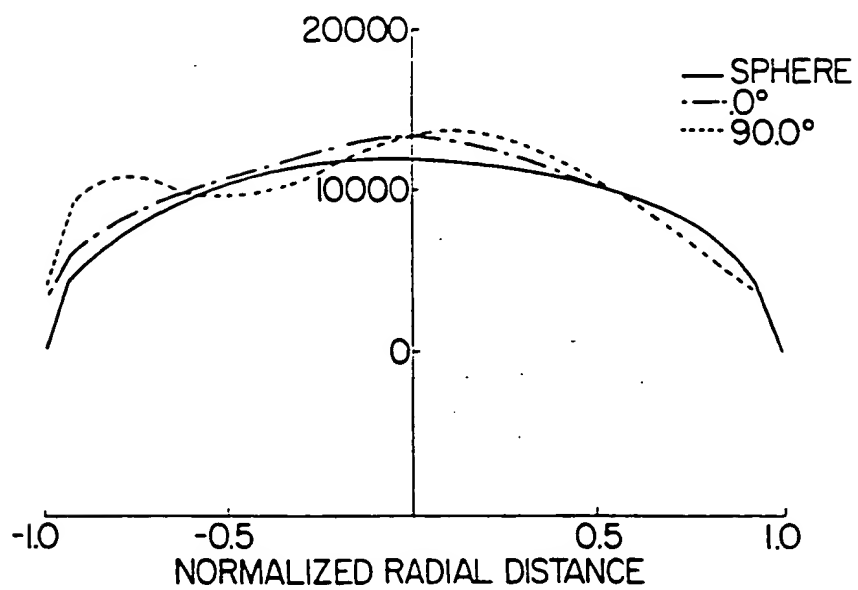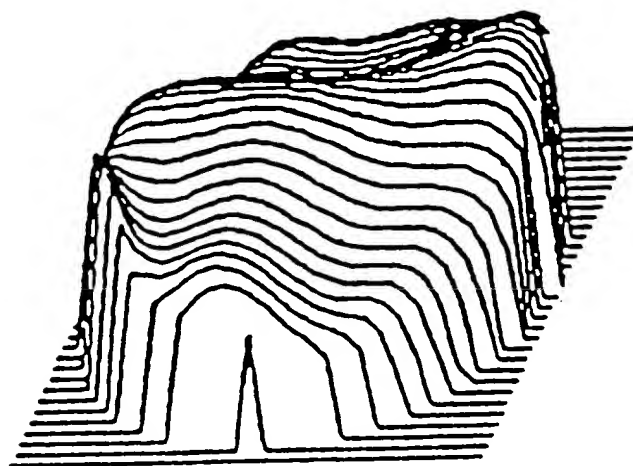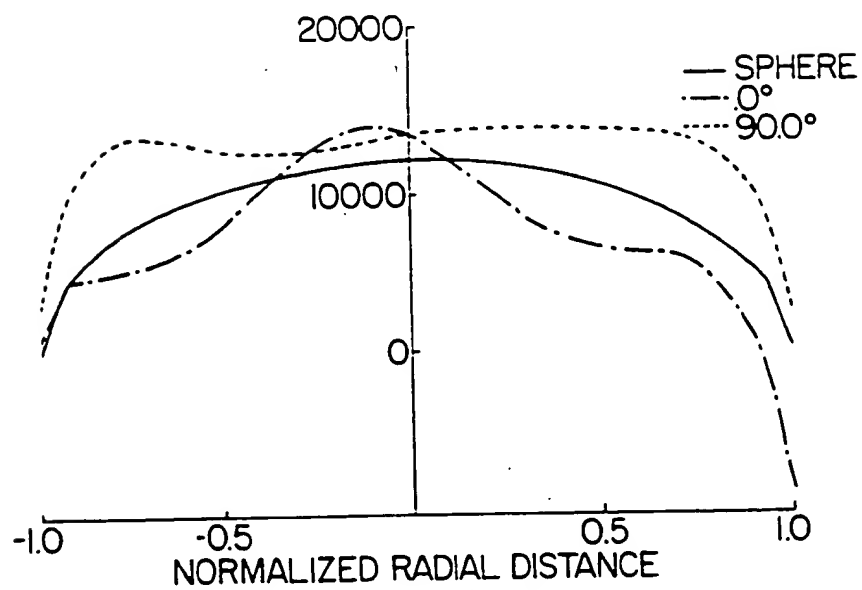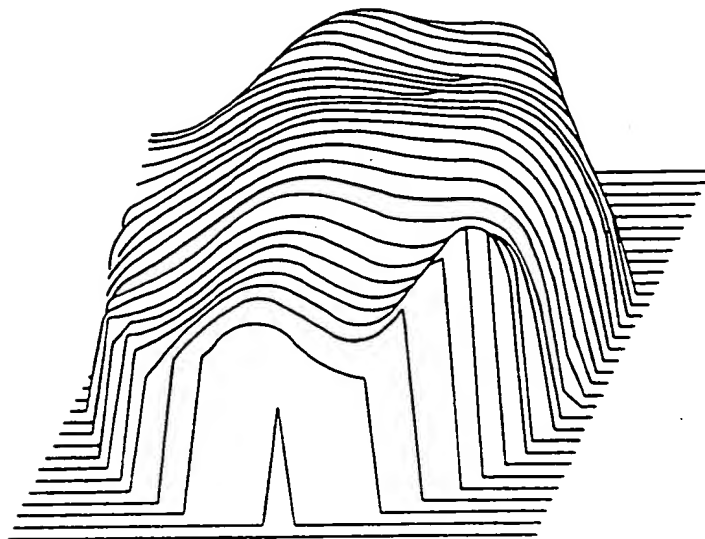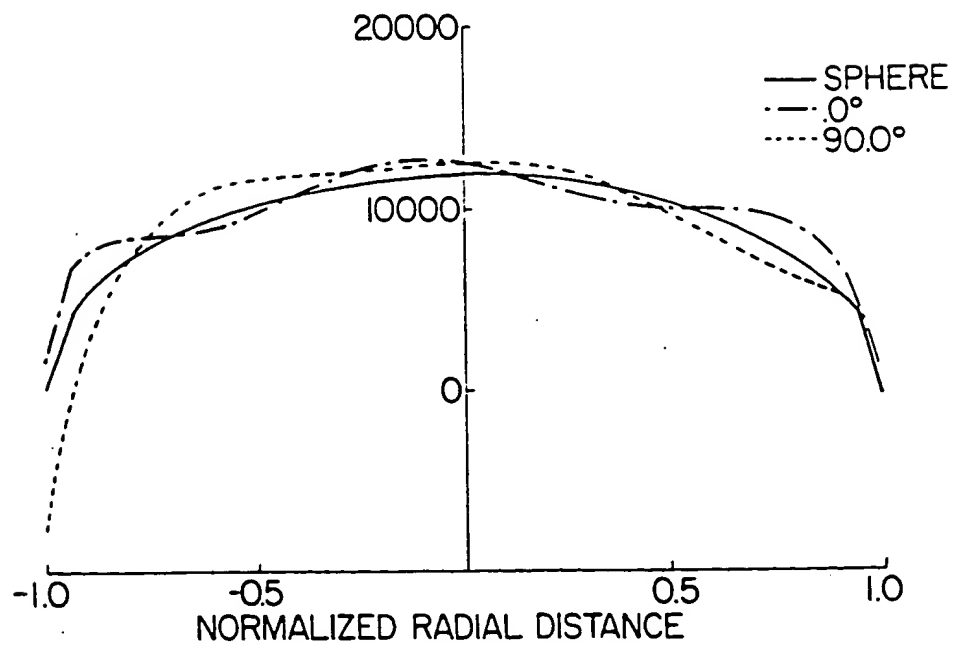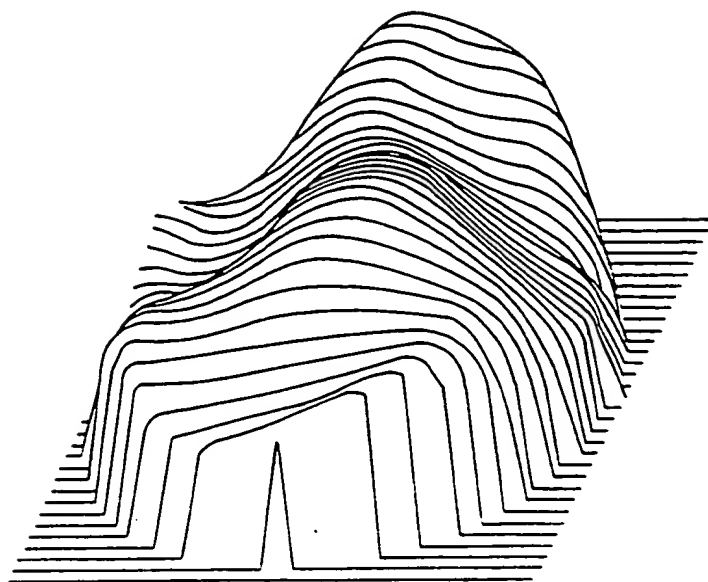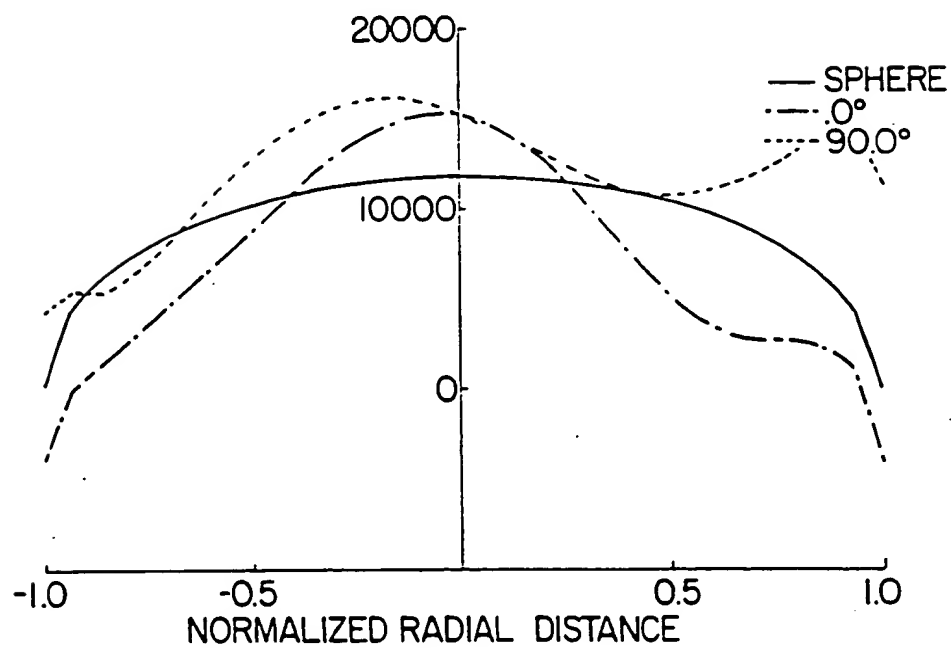
F I G. 14B

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 02/14
US CL :623/5

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 623/4, 5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,961,744, (KILMER ET AL.), 09 October 1990. See column 7 line 67 to column 8 line 5.	1-2
Y		3-14
Y, P	US, A, 5,318,047, (DAVENPORT ET AL.), 07 June 1994. See column 4, lines 44-62.	3-14

☐ Further documents are listed in the continuation of Box C.   ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance		
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 OCTOBER 1994	0 6 DEC 1994

Name and mailing address of the ISA/US	Authorized officer
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Form PCT/ISA/210 (second sheet)(July 1992)*